K102992 1/2

510(k) Summary of Safety and Effectiveness:
T2® RECON NAIL SYSTEM LINE EXTENSION

DEC 2 2 2010

Proprietary Name:	T2® Recon Nail System Line Extension
Common Name:	Intramedullary Nail
Classification Name and Reference:	Intramedullary Fixation Rod, 21 CFR §888.3020
Proposed Regulatory Class:	Class II
Product Codes:	87 HSB: Rod, Fixation, Intramedullary And Accessories
For Information contact:	Avital Merl-Margulies Regulatory Affairs Specialist Howmedica Osteonics Corp. 325 Corporate Drive Mahwah, NJ 07430 Phone: (201) 831-6365 Fax: (201) 831-3365
Date Prepared:	December 14, 2010

Description:
The T2® Recon Nail System is a family of IM (Intramedullary) Nails for various types of femoral fractures. This Special 510(k) submission is intended to address modifications to the T2® Recon Nail System cleared under K032898. The anterior to posterior curve is being modified as part of a line extension of the T2® Recon Nail System. The T2 Recon Nail System currently contains 2000mm anterior to posterior radius of curvature.

Intended Use:
The line extension to the T2® Recon Nail System does not alter the intended use of the predicate system as cleared in its' respective premarket notification. The indication for use of the subject nail is provided below.

Indications:
The T2® Recon Nail System indications include fixation of subtrochanteric, interochanteric, ipsilateral neck/shaft, communited proximal femoral shaft fractures, femoral fixation required as a result of pathological disease, and temporary stabilization of fractures of the femoral shaft ranging from the femoral neck to the supracondylar regions of the femur.

Proposed Modification:
The anterior to posterior curve is being modified as part of a line extension of the T2® Recon Nail System. The T2 Recon Nail System currently contains 2000mm anterior to posterior radius of curvature. The subject 1500mm radius of curvature nail design is substantially equivalent to

other devices currently marketed in the United States. A predicate device for the 1500mm radius of curvature design is the Gamma 3 Nail System cleared under K034002.

Summary of Data:

An engineering analysis of the new radius of curvature design has been performed to show that it does not affect the safety and effectiveness of the device. Potential risks analyzed include anatomical fit of the new radius of curvature as well as mechanical strength of the T2® Recon Nail. These risks have been investigated with use of failure mode effect analysis (FMEA) and prior mechanical testing which analyzed the critical loading areas of the device and demonstrate how the proposed radius of curvature does not affect device performance.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Howmedica Osteonics Corp.
% Ms. Avital Merl-Margulies
325 Corporate Drive
Mahwah, NJ 07430

DEC 2 2 2010

Re: K102992
Trade/Device Name: T2 Recon Nail System Line Extension
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: Class II
Product Code: HSB
Dated: October 7, 2010
Received: October 8, 2010

Dear Ms. Merl-Margulies:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K102992

Device Name: Line Extension to the T2® Recon Nail System

DEC 2 2 2010

Indications For Use:

The T2® Recon Nail System indications include fixation of subtrochanteric, interochanteric, ipsilateral neck/shaft, communited proximal femoral shaft fractures, femoral fixation required as a result of pathological disease, and temporary stabilization of fractures of the femoral shaft ranging from the femoral neck to the supracondylar regions of the femur.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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for M. Mellen

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K102992